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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,584	03/08/2004	Clark R. Baker JR.	TYHC:0149/FLE (P0409R)	1106

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EXAMINER	
RAMIREZ, JOHN FERNANDO	

ART UNIT	PAPER NUMBER
3737	

NOTIFICATION DATE	DELIVERY MODE
07/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip.legal@covidien.com

Office Action Summary	Application No.	Applicant(s)	
	10/796,584	BAKER, CLARK R.	
	Examiner	Art Unit	
	JOHN F. RAMIREZ	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-16 and 18-22* is/are rejected.

7)☒ Claim(s) *5 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/19/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.111

A request for continued examination under 37 CFR 1.111 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.111 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.111 and prosecution in this application has been reopened pursuant to 37 CFR 1.111. Applicant's submission filed on 02/09/10 has been entered.

Response to Arguments

Applicant's arguments have been fully considered, but are deemed not persuasive.

In relation to appellant's argument that the Diab et al. reference does not disclose detecting the presence of venous pulsation. The examiner of record notes that the Diab et al. reference in Figure 25B and in paragraphs 0389-0396 of the specifications discloses calculating the phase differences between the red and infrared signals and compares it with a threshold value to detect the presence of venous blood pulsation.

In relation to appellant's argument that the examiner failed to produce documentary evidence to demonstrate that "the primary cause of noise in transmissive pulse oximetry measurements is motion artifact caused by the movement of venous blood in the finger". The examiner is providing a technical document (Masimo - "Discrete Saturation Transform") to disclose that it is commonly understood in pulse

oximetry that the detected physiologic signals in response to both red and infrared light consist of desired signal portions as well as undesired signal or noise portions. The desired signal portions are proportional to one another through the arterial optical density ratio. The resultant is a reference signal that contains only noise portions.

Considering the finger for example, the venous blood in the vascular bed will be easily deformed during motion. In addition, the venous blood is a strong absorber of light. Hence, it can represent a significant contributor to the total optical density during motion episodes. During routine patient motions (shievering, waving, tapping, etc.), the resulting noise can be quite substantial and can easily overwhelm a conventional ratio based oximetry system. Having identified the venous blood as a significant contributor to noise during motion.

In response to the argument that the evidence submitted by the examiner in support of facts "well known" in the art at the time Appellant's application was filed is dated after the filling date of the present application. The examiner of record mistakenly cited the wrong date reference as evidence to support the official notice statement. As noted the new evidence submitted in this action is by the same assignee Masimo Corporation dated (1999-2000).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-16, 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diab et al. (US 2003/0036689) in view of Swedlow et al. (US 5,662,106) and further in view of non-patent literature *"Masimo Signal Extraction Pulse Oximetry"*.

With respect to claims 1-4, 6-16, 18-22, the Diab et al. patent teaches a system for detecting the presence of mixed venous and arterial blood pulsation in tissue, (abstract, paragraph 0019), obtaining a measure of a phase difference between said first and second electromagnetic radiation signals (paragraphs 0389-0391, fig. 25B, elements 694,692, 690), comparing said measure with a threshold value to form a comparison (paragraph 0387, fig. 25B, elements 660, 662,696); and detecting the presence or absence of venous pulsation using said comparison (paragraphs 0019, 0368). (NOTE: it is well known in the art that the primary cause of noise in transmissive pulse oximetry measurements is motion artifact caused by the movement of venous blood in the finger. See technical paper, "Masimo Signal Extraction Pulse Oximetry" (1999-2000), abstract, pages 476-477, 479-481 see sections: Effect of motion on pulse oximetry, Accurate saturation measurement during motion, The Masimo pulse oximetry model, In vivo example of the effects of motion on CPO and Masimo SET pulse oximetry, also see description of figs. 6 and 7).

Diab et al. do not disclose indicating the presence of venous pulsation to a caregiver if venous pulsation is present. However, the Swedlow et al. patent teaches an

indication of the presence of venous pulsation to a caregiver if venous pulsation is present (see abstract, fig. 1, element 30, and figure 4, col. 5, line 64 - col. 6, line 34).

It would have been obvious for a person of ordinary skill in the art, to modify the system disclosed by Diab et al., with the above discussed enhancements because such modification would provide a more accurate blood oxygen and pulse readings.

With respect to claims 2 and 14, Diab et al. discloses filtering the electromagnetic radiation signals to pass signals having frequencies at or near the pulse rate or harmonics (pars. 0329, 0385).

With respect to claims 3-4 and 15-16, Diab et al. illustrates in figures 26-30 the measurement of both signals red and infrared, in which each of the signals is relatively undisturbed by motion artifact over a time period (pars. 0411-0414).

With respect to claims 6 and 18, Diab et al. discloses a method for analyzing and correlating the measured signals (pars. 0014).

With respect to claims 7 and 19, Diab et al. discloses a frequency domain analysis and subtraction of the signals (pars. 0032, 0082, 0090, and 0402).

With respect to claims 8 and 20, the subtracting step by taking the complex conjugate of the signals and dividing it by the product of the magnitudes of the signals, it would have been an obvious design choice for one of ordinary skill in the art.

With respect to claims 9-11 and 21, Diab et al. discloses obtaining the measurement of the signals at or near a fundamental (first harmonic) or a harmonic of a pulse rate (pars. 0329, 0385, and 0400).

Allowable Subject Matter

Claims 5 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN F. RAMIREZ whose telephone number is (571)272-8685. The examiner can normally be reached on (Mon-Fri) 7:00 - 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737

/J. F. R./
Examiner, Art Unit 3737